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EXAMINER

PREBILIC, PAUL B

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/770,403
Filing Date: February 04, 2004
Appellant(s): MURPHY, TIMOTHY P.

Adam J. Cermak
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 3, 2009 appealing from the Office action mailed April 30, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct. No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

2002/0161414	FLESLER et al	10-2002
6,120,534	RUIZ	09-2000

Art Unit: 3774

5,690,644

YUREK et al

11-1997

Dictionary Definition of "swell" attached to this Examiner's Answer and found online at <http://encarta.msn.com/encnet/features/dictionary/DictionaryResults.aspx?refid=1861717507>

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-6, 8-10, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flesler et al (US 2002/0161414) in view of Ruiz (US 6,120,534). Flesler discloses a method of constricting the arteries leading to the small intestine with electrical stimulation but does not disclose placing a blood flow reducing device or an endograft inside the artery as claimed. However, Ruiz teaches that it was known to use physical restriction devices in arteries in order to restrict blood flow where needed; see the figures (particularly Figures 8A to 8C), the abstract, column 2, lines 5-58, and

Art Unit: 3774

column 7, line 21 to column 8, line 16. Therefore, it is the Examiner's position that it would have been obvious to utilize the endograft device of Ruiz in conjunction with or partly in place of the electrical stimulation device of Flesler to provide a set degree of minimal constriction that can be varied with the electrical stimulation means of Flesler or for the same reasons that Ruiz utilizes the same.

With regard to claims 3 and 8, the electrodes (200) of Flesler are devices placed around (i.e. in the area of) arteries of the small intestine including the superior mesenteric (110); see Figure 4. For this reason, the Examiner asserts that the claim language is clearly obvious over Flesler as modified by Ruiz.

With regard to claims 5 and 6, Flesler teaches putting electrodes in arteries leading to the small intestine. Since the gastroduodenal artery leads to the small intestine, the use of a constriction device therein is clearly suggested.

With regard to claim 12, Ruiz clearly teaches expanding the constrictor to adjust the amount of blood flow; see *supra*. For this reason, such would have been obvious when utilized in Flesler's method.

With regard to claim 13, a "swellable material" is interpreted broadly to mean a material that is able to increase in size or expand in size or shape; see <http://encarta.msn.com/encnet/features/dictionary/DictionaryResults.aspx?refid=1861717507>. Clearly, the middle portion of the Ruiz device is a material that can be increased in size and shape; see *supra*.

With regard to claim 14, the Examiner asserts that it would have been obvious to manage pain or discomfort by adjusting the constriction in order to maximize the benefit of the device where utilized.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flesler and Ruiz as applied to claims 1, 3-6, 8-10, and 12-14 above, and further in view of Yurek et al (US 5,690,644). Flesler fails to disclose moving a sleeve over the endograft and removing the sleeve within the artery. However, Yurek teaches that it was known to utilize sleeves over stents with inner catheters; see Figure 1 and column 3, lines 46-58. Therefore, it is the Examiner's position that it would have been obvious to utilize a sleeve with the stent and catheter of Flesler for the same reasons that Yurek utilizes the same, in order reduce artery tissue damage during delivery or to better control expansion of the constrictor.

Claims 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Flesler et al (US 2002/0161414) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Flesler et al (US 2002/0161414) in view of Ruiz (US 6,120,534). Flesler anticipates the claim language where electrical stimulation is used to constrict the arteries leading to the small intestine; see paragraphs [0020], [0011], and [0113]-[0114]. The reduction is considered to be permanent, fixed, invariable, and continuous to the extent required because these terms are terms of relative degree. Therefore, the Flesler device can and is used for permanent, fixed, invariable, and continuous way at least for a period of time.

Alternatively, one may not consider these terms of degree met by Flesler because Flesler teaches that the amount of reduction can be varied and transient. However, Ruiz teaches that it was known to the artery treatment art to make blood flow reduction more permanent, fixed, invariable, and continuous; see the previously cited portions thereof. Therefore, it is the Examiner's position that it would have been obvious to utilize the Ruiz device in addition to the Flesler device to provide a set degree of minimal constriction that can be varied with the electrical stimulation means or for the same reasons that Ruiz utilizes the same.

(10) Response to Argument

GROUND (a)

Beginning on page 15 of the Appeal Brief, the Appellant argues that the claimed invention is not obvious over Flesler and Ruiz because a NIH review panel concluded that Dr. Murphy's methods could cause severe pain and food fear in the patients (see page 16 of the Brief). In addition, it was argued that NIH review panel individuals are more skilled and knowledgeable in their fields than one of ordinary skill (see page 17 of the Brief). In response, the Examiner asserts that these individuals are not evaluating patentability, but rather, safety and efficacy; that is, they are evaluating a different issue and arguably using mutually exclusive criteria to arrive at their conclusions. Such criteria are more akin to Section 101 rather than to Sections 102 and 103. In other words, the panelists did not evaluate obviousness of the claimed methods, but rather, only looked at Mr. Murphy's methods for safety and efficacy. Furthermore, it is not clear that they were evaluating the methods as they are presently set forth in the present claims.

The NIH panel's mandate is to protect the public from dangerous or ineffective medical practices not to determine patentability. In fact, the Appellant admitted that ***“the NIH grant responses: (1) were prepared by a U.S. Government agency not concerned with patentability, but instead with safety and public health”***; see page 5, last paragraph of the response file July 12, 2007. Clearly, these individuals did not view the patent literature for patentability so they did not consider this question.

For example, statements made in the panel's Summary Statements pertaining to the state of the art were not correct. In particular, the Summary Statement of John Haller made of record on July 12, 2007 (see page 2, lines 6-9 of the text) suggests that reducing “mesenteric arterial blood flow” was “novel.” However, Flesler (US 2002/0161414) discloses that a method of doing this was known in the patent literature well before the publication of Summary Statement; see paragraph [0020] of Flesler. As a result, it is fairly clear that the panel and/or the author of this Summary Statement were not aware that this method was known. Moreover, it demonstrates that the panel members and/or the statement author were not evaluating the obviousness of the claimed invention in view of all the prior art.

Similarly, the Summary Statement by Christine Densmore made of record on July 12, 2007 (see page 2, third paragraph thereof), suggests that stents that restricted blood flow were not known on the date this Statement was published March 23, 2006. However Ruiz (US 6,120,534) demonstrates that the same was known to the patent literature at least 5 years before; see Figures 8A to 8C, the abstract, column 2, lines 5-

58, and column 7, line 21 et seq. Therefore, the Examiner asserts that the author of the Statement and/or the NIH panel was not knowledgeable of the state of the patent art.

In response to the evidence that the NIH panel evaluating Dr. Murphy's proposed method were of a high skill level, it is noted that only 1 of the 14 investigators (panel members) were on the scientific panel that evaluated Dr. Murphy's proposal (see the 14 biographies, curricula vitae, or the like made of record on April 7, 2008). For this reason, the backgrounds of 13 of the panel members are not clearly related to the present patentability determination. Furthermore, even though Dr. Burgess-Beusse was listed as a panel member on one of Summary Statements, the actual substance of the Summary Statement suggests that she was not aware of the state of the patent art at the time the statement was made.

Therefore, since the NIH panel's opinions were disconnected with patentability, they are considered to be of little significance with respect to patentability. As a result, the Appellant's arguments in this regard were similarly considered unpersuasive.

On page 20 of the Brief, the Appellant argues that Flesler devices do not necessarily control blood flow. However, it is clear from paragraphs [0113] to [0116] that constriction of the arteries inherently restricts blood flow in those same arteries.

The Appellant also argues that Flesler does not enjoy the presumption of operability and enablement because Flesler is a published patent application not a patent. However, Flesler has since issued as a patent containing the same disclosure; see US Patent 6,600,953.

Beginning on page 20 of the Brief, the Appellant argues that impermissible hindsight has been utilized by the Examiner because millions of medical articles have been published that did not allude to the proposed combination. It must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). It is unclear what basis the Appellant is using to suggest that millions of medical articles have published when only articles that are relevant to the claimed invention would be considered before one in the art.

In response to the separate arguments made pertaining to claim 14 that Flesler teaches away from the claimed combination, the arguments appear not to be commensurate with the scope of claim 14 that claims "*adjusting the second portion of the endograft to achieve a pressure change within a desired range so that abdominal pain not related to meals does not occur.*" Clearly, Flesler is designed to control the amount of vessel constriction "without significantly reducing the patient's comfort"; see paragraph [0116] of Flesler. Therefore, the method disclosed by Flesler is clearly consistent with the actual claim language.

Art Unit: 3774

GROUND (b)

The Appellant relies on the arguments presented in the traversal of ground (a) so the Examiner asserts that ground (b) should stand or fall therewith; see page 22 of the Brief.

GROUND (c)

Beginning on page 23 of the Brief, the Appellant places great weight on the modifier of permanent, fixed, invariable, or continuous to describe the reduction of blood flow to the intestines. However, since the length of the permanent, fixed, invariable or continuous treatment is not specified, Flesler meets the claim language to the extent that it can be given patentable weight because Flesler does permanently, fixedly, invariably, or continuously restrict blood flow for a period of time; see paragraphs [0020], [0011], and [0113]-[0114]. In paragraph [0116], the language “preferably, but not necessarily, the electrical energy is applied at times which are likely to produce maximum weight loss” suggests that the full on mode of applying electrical energy was contemplated.

Alternatively, even if one is not convinced that Flesler teaches permanent, fixed, invariable, or continuous application of electrical energy, the Examiner asserts that the same is clearly obvious in that the transient application of stimulus is merely a preference; see paragraph [0113]. Since Ruiz teaches permanent constriction was known to the art, the utilization of Flesler method to permanently constrict blood flow would have been considered clearly obvious to an ordinary artisan.

It must be emphasized that a preference for a particular embodiment or mode of operation is not a teaching away from a non-preferred embodiment. As stated in the MPEP in section 2141.02, **“the prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed....”** *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004)

On page 25 of the Brief, the Appellant argues that Flesler does not teach a combination of therapies and further reductions of blood flow would not have been obvious. However, since Flesler teaches that the use of combinations of therapies was contemplated (see paragraph [0114]), the use of combinations of therapies to reduce blood flow would have been considered clearly obvious. Moreover, Flesler also teaches application of electrical energy to multiple blood vessels (see Figure 4 and paragraph [0114]) so the combination of therapies to reduce blood flow is considered clearly suggested.

On page 29 of the Brief, the Appellant reiterates that combinations of therapies were not contemplated by Flesler. However, it is clear that Flesler was not limited to the constriction of one blood vessel so it would have been clearly obvious to combine the alternative therapy of Ruiz with Flesler in that they are both performing the same function. The combination claimed is a mere combination of known elements to achieve a predicable result; see MPEP 2143.

Art Unit: 3774

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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